

DEVICES AND METHODS FOR CONTROLLING INITIAL MOVEMENT OF AN ELECTROSURGICAL ELECTRODE

This application claims priority to U.S. Provisional Application Serial No. 60/426,030,
5 filed on November 13, 2002. This invention relates to devices and methods that may, but do not
necessarily, involve the use of a target tissue localization device, such as shown in U.S.
Application Serial No. 09/677,952, filed October 2, 2000, now issued as U.S. Patent No.
6,325,816, in conjunction with an electrosurgical loop-type cutter, such as shown in U.S.
Application Serial No. 09/844,661, filed April 27, 2001; U.S. Application Serial No. 09/588,278,
10 filed June 5, 2000, now issued as U.S. Patent No. 6,530,278; and U.S. Application Serial No.
10/045,657, filed November 7, 2001. All of the above-mentioned patents and applications are
herein expressly incorporated by reference in their entirety.

Field of the Invention

15 The present invention relates generally to an electrosurgical electrode system that is
capable of excising a tissue sample through the creation of an arc at the electrode.

Background

20 Typical electrosurgical procedures, such as cutting or cautery procedures, are performed
with a hand held device, which the user can manipulate as the RF energy is delivered in order to
facilitate the creation of the desired effect at the electrode. The ability to visually see the
electrode and to change the proportion of the electrode that is held in contact with the tissue
allows the user to adjust the motion or position of the device with respect to the activity observed
at the electrode to compensate for the constant power output of a commercial electrosurgical

generator and to force the generator to achieve the desired effect. With a percutaneous procedure, in particular an automated, percutaneous procedure, this type of user-based control is not possible, since the electrode is, in many cases, not visible. And in the case of automated control, the effects occur too quickly to allow human reaction. In this case, it is advantageous to have an automated method to evaluate the effect at the electrode and a method to determine when specific events have occurred and initiate the appropriate action. Of specific concern in a procedure requiring the cutting or excision of tissue is the creation of an arc at the electrode, since an arc permits the vaporization of tissue, which is the phenomenon that creates the cut. This invention utilizes the measurements of the electrical characteristics of the tissue and correlates them to a physical effect at the electrode, which is then used to initiate or control an automated sequence.

Summary of the Invention

The present invention relates to devices and methods for using an electrosurgical electrode to excise a tissue sample from a patient. More particularly, the invention provides a system that includes a means for monitoring the appropriate time to initiate movement of the cutting device.

In one embodiment, the electrosurgical electrode assembly includes a cutting device having a catheter with a proximal and distal end. The cutting device also has an electrode carried by the distal end of the catheter. The proximal end of the cutting device is a handpiece that may be reusable or disposable, or a combination thereof. In particular, the handle of the handpiece may be reusable and the electrode inserted into the handle may be disposable. A controller is connected to the cutting device. A data acquisition system is connected to the controller that is

capable of monitoring voltage and current output. The system also contains a microprocessor connected to the data acquisition system, which is capable of processing voltage and current data from the data acquisition system. An electrosurgical generator is also connected to the data acquisition system. In operation, the controller initiates movement of the electrode upon arc
5 initiation at the electrode.

In another embodiment, the system also includes an electrically isolated switch connecting the data acquisition system and the controller. The electrically isolated switch may be an optical switch.

In another embodiment, the controller, data acquisition system, electrosurgical generator,
10 and microprocessor are integrated into a single control unit. The control unit may be able to drive DC motors that are located in the reusable handpiece of the cutting device.

In another embodiment, the electrosurgical electrode assembly includes a cutting device having a catheter with a proximal and distal end. The cutting device also has an electrode carried by the distal end of the catheter. The proximal end of the cutting device is a handpiece that may
15 be reusable or disposable, or a combination thereof. In particular, the handle of the handpiece may be reusable and the electrode inserted into the handle may be disposable. A controller is connected to the cutting device. A data acquisition system is connected to the controller that is capable of monitoring voltage and current output. The data acquisition system is providing feedback information to the controller through the arc detection cable. An electrosurgical
20 generator is also connected to the data acquisition system. The output from the electrosurgical generator passes through the data acquisition system and the controller to the patient through the handpiece. In operation, the controller switches on the electrosurgical energy to the electrode and initiates movement of the electrode upon arc initiation at the electrode based on feedback

information from the arc detection cable. In an alternative embodiment, the system may also include a microprocessor connected to the data acquisition system. The microprocessor may include logic to calculate the load (or electrical) impedance so that it may determine the presence of an arc.

5 In yet another embodiment, the electrosurgical electrode assembly includes a cutting device having a catheter with a proximal and distal end. The cutting device also has an electrode carried by the distal end of the catheter. The proximal end of the cutting device is a handpiece that may be reusable or disposable, or a combination thereof. In particular, the handle of the handpiece may be reusable and the electrode inserted into the handle may be disposable. The
10 assembly also includes a control unit connected to the cutting device. This integrated control unit contains an electrosurgical generator connected to the cutting device and a data acquisition system connected to the generator that is capable of monitoring voltage and current output. The control unit also contains a microprocessor connected to the data acquisition system, which is capable of processing voltage and current data from the data acquisition system, and a controller
15 connected to the data acquisition system. In operation, the controller initiates movement of the electrode upon arc initiation at the electrode.

 In another embodiment, the microprocessor of the systems described above includes logic to calculate the load (or electrical) impedance from the current and voltage output. By monitoring the change in the load (electrical) impedance value, the presence of an arc can be
20 determined. The presence of the arc could also be determined by monitoring any one, or a combination, of the following electrical characteristics: electrical impedance, a change in electrical impedance, voltage, a change in voltage, current, or a change in current.

In another embodiment, the systems include a return electrode connected to the electrosurgical generator.

In yet another embodiment, the electrode has a proximal part and a distal part. The distal part of the electrode is movable between a retracted state and an outwardly extending operational state. A first driver may also be operably coupled to the electrode, where the first driver can move the electrode from the retracted state and/or rotate the electrode about its axis in order to separate a tissue section from the surrounding tissue by moving the electrode. In addition to rotating the electrode, the electrode may also be moved translationally or in any other way to effect separation of the tissue section from the surrounding tissue.

The methods of the present invention relate to controlling the initial movement of an electrosurgical electrode. Energy is delivered to an electrosurgical electrode. The electrical characteristics associated with the electrosurgical electrode are then monitored. This monitoring step may include monitoring any one, or a combination, of the following electrical characteristics: electrical impedance, a change in electrical impedance, voltage, a change in voltage, current, or a change in current. The initiation of an arc is then determined based on the monitoring step. The electrosurgical electrode is then moved once the arc has been detected. In one embodiment, the electrode may be moved automatically once the arc has been detected. The energy being delivered to the electrosurgical electrode may then be adjusted based upon the monitoring step in an effort to help maintain an effective arc. In addition, the speed of the electrosurgical electrode may also be adjusted based on the monitoring step in an effort to help maintain an effective arc.

The methods of the present invention also relate to controlling the operation of a percutaneously-placed electrosurgical electrode of an electrosurgical device. Energy is first

delivered to a percutaneously-placed electrosurgical electrode to create an arc at that location, while the electrode is stationary. The electrical characteristics associated with the electrosurgical electrode are then monitored. The electrical characteristic being monitored may be any one, or a combination, of the following: electrical impedance, a change in electrical impedance, voltage, a change in voltage, current, or a change in current. Once the creation of a cutting arc is established between the adjacent tissue and the electrode, the controller initiates movement of the electrode to effect separation of the tissue section from the surrounding tissue. The energy being delivered to the electrosurgical electrode may then be adjusted based upon the monitoring step in an effort to help maintain an effective arc.

In another method of controlling the operation of a percutaneously-placed electrosurgical electrode of an electrosurgical device, the percutaneously-placed electrosurgical electrode may be moved along a predetermined path while energy is being delivered. An electrical characteristic associated with the electrode may be monitored at the electrode. The electrical characteristic being monitored may be any one, or a combination, of the following: electrical impedance, a change in electrical impedance, voltage, a change in voltage, current, or a change in current. An expected position of the electrode along the predetermined path may also be monitored. The energy delivered to the electrode may then be adjusted based on the monitoring steps of the electrical characteristic and expected position in order to maintain an effective arc. In one embodiment, the electrical characteristic being monitored is electrical impedance.

As discussed above, the devices of the present invention monitor an electrical characteristic of the electrosurgical electrode. The electrical characteristic being monitored may be any one, or a combination, of the following: electrical (or load) impedance, a change in electrical (or load) impedance, voltage, a change in voltage, current, or a change in current. In a

preferred embodiment, the system monitors for an electrical impedance value over 500 ohms. In another preferred embodiment, the system monitors for an electrical impedance value over 2-times a baseline electrical impedance value. In yet another preferred embodiment, the system monitors for an electrical impedance value of 2.5-times a baseline electrical impedance value.

5 Brief Description of the Drawings

Fig. 1 depicts a system for using an electrosurgical electrode.

Fig. 2 depicts a diagram of the IO controller of Fig. 1.

Fig. 3 depicts a diagram of the DAS data acquisition system of Fig. 1.

Fig. 4 depicts an integrated system for using an electrosurgical electrode with a fully
10 integrated controller and generator.

Fig. 5 depicts another integrated system for using an electrosurgical electrode with a fully integrated controller and generator.

Detailed Description

15 A first embodiment uses a commercially available RF generator along with an "IO" Control Box that controls the RF output to the electrode or loop-type cutter and contains a stepper motor drive to deploy and rotate the loop electrode. The RF activation, loop deployment and rotation are an automated sequence controlled by a stepper motor drive unit within the IO controller. One activation technique includes actuating the RF for approximately 400
20 milliseconds prior to the start of the deployment/rotation of the loop, in order to allow time for an arc to be established at the loop electrode. (There is an additional 100 millisecond delay induced by the loop deployment mechanism, for a total delay of 500 milliseconds.) This type of open loop operation causes two potential areas of inefficiency. First, the arc could be created early in

the 500 millisecond period, causing excessive damage to the tissue while the electrode is arcing prior to the start of deployment/rotation. The second, more severe possibility is that the rotation sequence would be started prior to the creation of an arc, causing an incomplete cut or damage to the loop electrode, resulting in an inadequate tissue sample being obtained.

5

To provide more repeatable performance, the creation of a closed-loop system has been proposed. Review of the data collected from both clinical and bench testing has indicated that there is a significant difference in the load impedance when the electrode is arcing and when it is merely delivering RF energy to the tissue. This is probably the result of two different factors, the first being the desiccation of tissue surrounding the electrode (and removal of electrolytic solution) and the second being the creation of a gas-filled space around the electrode. By monitoring the load impedance during operation, a device could be constructed that detects when an arc has been created, and could initiate the deployment/rotation of the loop electrode.

15 As depicted in Fig. 1, the first embodiment makes use of the Artemis Data Acquisition System ("DAS") 10, Artemis Medical, Inc., Hayward, California, validated hardware that collects RF voltage and current data during the operation of the system. This data is fed to a data-acquisition card (National Instruments DAQ 516) in a microprocessor 14 (in a laptop computer), which then uses this voltage and current data to calculate the delivered power and load impedance. In addition to the analog inputs required to monitor voltage and current, this data-acquisition card contains digital output channels which could be used to signal the stepper motor driver that the movement, i.e., deployment and/or rotation sequence is to be initiated. Fig. 1 shows the electrical interconnection of the components used in the system.

System Overview:

IO Controller 18: Additional signals need to be brought into the IO Controller 18, so that the motor deployment/rotation sequence can be initiated once an arc has been detected.

5 There are an additional two unused inputs on the Si5580 Stepper Motor Driver 19 that have been wired to a unique connector 17 on the back panel of the controller 18. The circuit is shown in Fig. 2.

The operating software for the Si5580 drive unit 19 has been modified to check the status
10 of these signals prior to starting the motor sequence. Once the arc detection routine has been completed, the "Detect Routine Complete" signal is transmitted from the laptop computer 14 through the DAS Data Acquisition System 10 and to the Si5580 drive unit 19. When this signal is received, and if the "Arc Initiated" signal is present, the deployment/rotation sequence is initiated. If an arc was not detected, the "Detect Routine
15 Complete" signal is generated absent the "Arc Initiated" signal, instructing the Si5580 drive unit 19 to de-energize the RF output and abort the remainder of the sequence. In order to permit the operation of the IO Controller 18 without the DAS Data-Acquisition System 10, the Si5580 drive unit 19 checks if the "Detect Routine Complete" signal is absent initially, in which case the sequence is initiated using the 400 millisecond delay,
20 without using any of the arc detection logic.

DAS Data-Acquisition System 10: As seen in Fig. 3, to electrically isolate the DAS System 10 from the IO Controller 18, the digital signals on the DAQ 516 card 20 were

connected to two ISOCOM optically coupled isolators 22, 24, which provide 5.3 kVRMS of electrical isolation between the input and output. Optically coupled isolators 22, 24 are a means of transmitting a signal between two systems without having any direct electrical connection. In this system, the signals of the DAQ 516 cards 20 are connected to the inputs of the isolators and the outputs of the isolators are wired to a connector 30 on the enclosure, which is ultimately connected to the IO Controller 18 and the inputs to the Si5580 drive unit 19. When the digital signals on the DAQ card 20 are activated, a light emitting diode inside the isolator turns on, which then activates a photo-transistor on the output of the isolator. This photo-transistor provides the signal to the Si5580 drive unit 19, which allows light, rather than electrons, to become the transmission medium. This ensures that there is no possibility of any hazardous electric energy being transferred from one system to the other.

The Visual Basic program used for data-acquisition from the DAS Controller may be modified to check for an increase in impedance, which indicates that an arc has started. What is unique about this approach in the field of electrosurgery is the concept of monitoring the RF voltage and current output, thereby determining the load impedance (or other characteristic associated with the electrode) and using an observed change in that load impedance to start an automated procedure. It would also be possible to achieve a similar result by monitoring other electrical characteristics at the electrode, such as the delivered current or voltage, to determine when an arc has been initiated.

A review of the data files from bench and clinical testing indicated that typically the load impedance was below 400-450 ohms when the electrode had not initiated an arc. Once an arc was initiated, the load impedance increased to at least 700 ohms, and in most cases exceeded 1000 ohms. This information was taken into account to specify an initial value of, for example, 500 ohms as the threshold to determine when an arc has started. The software is preferably structured to allow the user (product designer) to alter this value to further refine the arc detection scheme.

A timeout routine may be incorporated into the software as a safety feature. If the arc impedance threshold is not attained within, for example, one second, indicating that an arc has not been created, the RF is de-energized, and the routine is aborted and the user is alerted of this fact.

There may be two digital signals used for the arc detection routine, "Detect Routine Complete" and "Arc Initiated". When the software determines that an arc has been established, it sets the "Arc Initiated" signal high, and then indicates that the detection routine has completed by initiating a high-to-low transition of the "Detect Routine Complete" signal. This logic is structured in such a way as to minimize the risk of a false positive signal being sent to the controller, since it is unlikely that a single failure would cause both the "Arc Initiated" signal to be set high and the "Detect Routine Complete" signal to be set low.

In another embodiment, as depicted in Fig. 4, the functionality of the RF (electrosurgical) generator 36, DAS 10, IO Controller 18, and microprocessor 14 is integrated into a single control

unit 40. In yet another embodiment, the control unit 50 contains a power supply 52, RF
(electrosurgical) generator 36, controller 54, DAS 10, and microprocessor 14 (see Fig. 6). These
integrated systems allow the motor drive sequence and RF output to be controlled by a single
microprocessor 14, which enhances the communication between the subsystems and allow
5 additional signal processing. With this type of integrated system, it is possible to refine the
control algorithms.

RF Output: With the other embodiment, the user sets the RF output power on the
commercially available generator at the start of the procedure. There is no provision for
10 an automated adjustment of this RF output power, since there is no communication
between the microprocessor 14 (in the laptop computer) and the generator 36. With the
integrated system of the preferred embodiment, however, it would be possible not just to
signal the motor drive system to start movement or rotation in response to a change in
load impedance, but it would also allow the RF output to be adjusted to compensate for
15 changes in load condition. In contrast to other methods, which vary the speed of the
cutting electrode through the tissue in response to changes in the load impedance, varying
the RF output is advantageous since the system responds faster electrically than
mechanically. With the preferred integrated system embodiment, the system monitors
the performance during the automated sequence and makes adjustments during operation
20 to reduce the incidence of failures. For example, if during the rotation sequence, the load
impedance started to fall, the failure of the arc could be predicted, and the RF output
increased in an effort to mitigate this failure. It would also allow the potential for
adjusting the RF output with respect to the position of the cut wire, as it is likely that the

RF output requirement is different at different points in the wire deployment/rotation sequence. As the cut process continues and as the sample is physically detached from the bulk tissue, the electrical characteristics may change, and the performance of the system could possibly be enhanced by making adjustments to the output during rotation to compensate for these changes. This could also be employed to use a higher output power to establish an arc, then cause the system to switch to a voltage control mode, where the output voltage rather than power is regulated, once the wire deployment process is started. This type of control provides an advantage, since a fixed output voltage causes the delivered power to increase in response to a lower load impedance, and to decrease in response to a higher load impedance. In this fashion, when the arc is created, and the impedance increases, the power is automatically reduced to mitigate thermal damage.

The RF algorithm control includes the following steps:

1. Find baseline impedance – deliver low power (approximately 5 W) for approximately 0.2-0.5 seconds and monitor load impedance, this sets a baseline value of impedance.
2. Initiate Arc – under power control, deliver high power output until an arc is detected by observing the load impedance increase approximately 2 to 3 times above baseline, preferably approximately 2 times above baseline. The high power output can be in the range of approximately 100-200 W. In a preferred embodiment, the high power output is approximately 170 W.
3. Dwell approximately 25-150 ms, preferably approximately 40 ms, allowing for the arc to stabilize.

4. Deploy cut wire – switch to fixed output voltage and extend electrode.

The fixed output may be in the range of approximately 200-350 V. In a preferred embodiment, the fixed voltage output should range from approximately 240-260 V.

5. Dwell approximately 0-150 ms, preferably approximately 20 ms, maintaining voltage control and allowing the arc to stabilize.

6. Start electrode rotation – deliver fixed output cut voltage. This may be in the range of approximately 150-300 V, preferably 240-260 V..

7. Monitor impedance and recover arc if needed– monitor impedance and when it falls below approximately 2X the baseline value used in step 2, output approximately 170 W to re-initiate the arc.

Motor Control: Using a single processor to control the RF output and the motor drive system also allows the motor speed to be regulated in response to changes in the load impedance. Different anatomical structures are comprised of different types of tissue, each of which has different electrical and physical properties. In general, there is a relationship between the density of the tissue and its electrical impedance. Dense, fibrous tissue typically has a lower level of hydration, which reduces its conductivity and increases its impedance. If this is taken into account, the arc detection system could also be used to regulate the speed of the motor drive system so that it is optimized for the specific tissue encountered. For example, once an arc is created, it would be possible on dense tissues for the cutting process to be further enhanced by slowing the speed of the electrode. On spongy or fatty tissues, which are relatively easy to cut, the thermal damage to the surrounding areas could be reduced by increasing the speed of the

electrode, thereby minimizing the RF exposure. Furthermore, by monitoring the status of the tissue electrical properties, the system could allow a dwell time at specific points in the sequence, which could allow the arc to become more established and provide an improved cutting effect once motion is resumed. It could also determine if the arc at the electrode dissipated, at which point the motor could be stopped and the arc initiation and detection routine repeated.

User Control

Handpiece: The reusable handpiece has two buttons on it for user control of the system. One button is a “select” button that allows the user to toggle from one step of the procedure to the next. The other button is an “activate” button that allows the user to activate that step. For user convenience, the system also has an optional footswitch with two buttons that function as “select” and “activate” under the same manner as the handpiece switches.

In operation, in one embodiment, the user may perform the following steps:

Home the reusable handpiece – This step moves the motors and the mechanisms to a first position ready to receive the disposable insert. In particular, this step activates motor control to move the cut wire mechanism (CWM) and the Python/hook wire mechanism (PHWM) to a position ready to receive the disposable electrode insert.

Insert the disposable electrode– The user inserts the disposable electrode into the reusable handpiece and secures it with a ¼ turn rotation. The disposable electrode has an ID resistor in it that the reusable handpiece detects and communicates to the control box. If the resistance value is within a certain range, the system automatically programs itself

for the proper disposable. The resistance value for a 15 mm cut disposable electrode is different than the resistance value for a 25 mm cut disposable electrode.

5 *Ready for insertion* – The disposable electrode comes with the capture Python and hook wire fully deployed. These are retracted into the shaft of the disposable electrode for device insertion into the patient.

10 *Insertion* – The user will create a skin incision to get the tip of the device under the skin. From there, the user gently pushes the device toward the intended target, e.g., a biopsy target. If tissue resistance is felt, the user can activate the RF electrodes at the tip of the instrument by tapping on the “activate” button. The details of the reusable handpiece, including the placement of the electrodes of the penetrating tip, are described in related U.S. Application Serial No. 10/374,582, filed on February 25, 2003, entitled “Tissue Separating Catheter Assembly and Method,” the entirety of which is hereby expressly incorporated by reference in its entirety.

15 *Cut & capture sample* – Once the device is in the proper position, the user activates the cut and capture sequence. Holding down the “activate” button for the duration of the cut activates the following steps: sending RF energy to the electrode, detecting the arc, moving the electrode, turning off the RF energy, stopping the electrode movement, and extending the hook wires and python. The user can also interrupt the cut sequence if desired.

20 *Remove system from patient* – The user withdraws the device with the cut sample from the patient.

Remove the sample from the device – The user hits the “activate” button to make the Python and hook wire retract from the sample. Once withdrawn, the user can use forceps to remove the cut sample from the device.

Remove the disposable from the reusable – The user releases a spring latch, counter-rotates the disposable electrode by $\frac{1}{4}$ turn, and removes the disposable electrode from the handpiece. The reusable handpiece can then be homed for insertion of another disposable electrode.

In a preferred embodiment, the integrated control box allows the user to start the cut sequence and stop it at any point. The user may elect to stop due to patient discomfort, or distraction in the room, etc. By releasing the “activate” button during the cut sequence, the RF energy is turned off and electrode movement stops. The system keeps track of the motor position to later re-activate and complete the movement. To restart the movement, the user again holds down the “activate” button and the system will repeat the startup RF algorithm above from the place it left off

Percutaneous devices can benefit from using an RF activated penetrating electrode to ease placement. In yet another embodiment, RF energy is delivered to the distal tip of the device, creating a small arc to make an incision during penetration. Typically, the activation periods of such a device are very short, perhaps 500 to 1000 milliseconds. In this case, it is important to establish an arc as quickly as possible, but to minimize the power delivery in order to prevent damage to surrounding tissues. The same arc detection scheme could be employed to determine when an arc has been

created, and then to limit the maximum power or voltage delivered to the tissue. It could also be used to reduce the time required to initiate an arc at the electrode, by delivering a higher initial output power, which would then be reduced once the arc was detected.

Although the foregoing invention has, for purposes and clarity of understanding,
5 been described in some detail by way of illustration and example, it will be obvious that certain changes and modifications may be practiced which will still fall within the scope of the appended claims.